IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
Washington, DC 20231

Re: U.S. Utility Patent Application No.:
Filed: 09/553,094
For: Nucleic Acid Molecules and Other Molecules Associated With Plants
Inventors: Scott E. Andersen et al.
Atty. Docket: 38-21(15503)B

Sir:

Transmitted herewith for appropriate action by the U.S. Patent and Trademark Office (USPTO) are the following documents:

1. Appellant's Brief (in triplicate);
2. Certificate of mailing for Appellant's Brief; and
2. (1) Return receipt-postcard.

It is respectfully requested that the attached postcard be stamped with the date of Filing of these documents, and that it be returned to us.

Please charge the statutory fee of $320.00 for filing of Appellant's Brief to our deposit account 13-4125. A duplicate copy of this page is attached.

In the event that extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned. Applicant's do not believe any additional fees are due in conjunction with this filing. However, if any fees under 37 C.F.R. § 1.16 or § 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to our Deposit Account No. 13-4125, referencing matter number 38-21(15503)B.

Respectfully submitted,

Pamela J. Sisson

Date: March 17, 2003

Pamela J. Sisson (Reg. No. 53, 600)

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AF/1631

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re applications of:

Scott E. Andersen et al.

Appln. No.:09/553,094

Filed: April 18, 2000

For: Nucleic Acid Molecules and Other Molecules Associated With Plants

Art Unit: 1631

Examiner: Marjorie A. Moran

Atty. Docket: 38-21(15503)B

Commissioner for Patents
Washington, DC 20231

Certificate of Mailing

I hereby certify that this "Appellant's Brief", is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

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Gracie Williams
(Signature)

193

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:			
Scott ANDERSON *et al.*		Art Unit:	1631
Appln. NO.:	09/553,094	Examiner:	Marjorie A. MORAN
Filed:	April 18, 2000	Atty. Docket:	16517.001/ 38-21(15503)B
For:	**Nucleic Acid Molecules and Other Molecules Associated with Plants**		

APPELLANT'S BRIEF

Commissioner for Patents
Washington, DC 20231

Sir:

This is an Appeal from the Rejection of all claims pending in the above-described patent application. A Notice of Appeal was filed on January 15, 2003. The statutory fee of $320.00 for submitting this Brief should be charged to deposit account number 13-4125. *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

The Applicants are unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claims 1 and 8 are pending. Claims 2-7 were canceled. Appellant appeals all of the rejections of claims 1 and 8.

4. Status of Amendments

Applicants have not filed any responses subsequent to Final Rejection in this case.

5. Summary of Invention

The invention is directed to a substantially purified nucleic acid molecule reciting the sequence of an expressed sequence tag ("EST") and its complement. The nucleic acid molecule was derived from a cDNA collection prepared from *Zea mays* tissues. More particularly, the invention is directed to: a substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1 (claim 1) and a substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1 (claim 8).

6. Issues

The issues in this Appeal are:

(a) whether claims 1 and 8 are unpatentable under 35 U.S.C. § 101 for alleged lack of patentable utility due to its not being supported by a specific, substantial, and credible utility, or, in the alternative, a well established utility; and

(b) whether claims 1 and 8 are unpatentable 35 U.S.C. § 112, first paragraph for alleged lack of enablement because the claimed invention purportedly lacks utility; and

(c) whether claim 1 is unpatentable under 35 U.S.C. § 112, first paragraph for alleged insufficiency of written description.

1. Grouping of Claims

Patentability of claims 1 and 8 is addressed together in Sections 8.A through 8.C below. Patentability of claim 1 is also addressed in Section 8.D below. A copy of the claims on appeal is attached hereto as Appendix A.

2. Argument

A. Summary of Appellant's Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met their part of the bargain – they have proven that the claimed nucleic acid molecule, in its current form, provides at least one specific benefit to the public, *e.g.*, the ability to identify the presence or absence of a polymorphism in a population of corn plants. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit. Because the claimed nucleic acid molecule provides at least this benefit, they satisfy the utility requirement of 35 U.S.C. § 101.

Because the specification teaches how to make and use the claimed nucleic acid molecule for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

Applicants have shown that the claimed nucleic acid molecule actually works for that and other utilities disclosed and described in the specification, and so both enablement rejections must be reversed. Applicants have proven that one skilled in the art is able to use the claimed nucleic acid molecule for at least one disclosed utility, namely use as a genetic marker for genetic mapping. The law clearly establishes that the enablement requirement is satisfied if at least one mode of making and using the invention is enabled. Because Applicants have proven that the claimed nucleic acid molecule works for the disclosed utility, the enablement requirement of 35 U.S.C. § 112 has been met.

Furthermore, Applicants have provided an adequate description of the claimed nucleic acid molecule that demonstrates Applicants' possession of the claimed invention. The genus of the claimed nucleic acid molecules, *i.e.*, nucleic acid molecules "comprising" SEQ ID NO: 1 have been described by the recitation of a "basic and novel" common structural feature – the nucleotide sequence of SEQ ID NO: 1 – which distinguishes them from nucleic acid molecules not in the claimed genus. Because the specification demonstrates that Applicants had possession of (and have provided an adequate description of) the claimed genus of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112.

B. **The Claimed Nucleic Acids Have Legal Utility**

Pending claims 1 and 8 were erroneously rejected under 35 U.S.C. § 101 because the claimed invention was allegedly not supported by "a specific, substantial, and credible utility, or,

in the alternative, a well established utility" as outlined in the Revised Interim Utility Guidelines Training Materials ("Interim Guidelines"). *See* Final Action mailed October 22, 2002 ("Final Action") (Paper No. 11) at page 3.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "comparative sequence analysis or to identify sequence motifs"; "to transform plants, to determine association with polymorphic sites, to determine a pattern or level of protein expression, to detect mutations, or to reduce protein expression"; and to obtain other nucleic acid sequences, to identify mutations and polymorphisms, to assist in genetic mapping, and as markers. *See* Office Action mailed February 15, 2002 (Paper No. 9) at pages 4-5. However, despite this admission and numerous uses cited throughout the specification, the Examiner contends that none of these utilities constitutes a "substantial" or "specific" utility as defined in the Interim Guidelines.[1] Applicants respectfully disagree. The application of the Interim Guidelines ignores the presently disclosed utilities and contravenes well-established doctrines of utility developed in the courts.

It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). As acknowledged by the Examiner, the

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[1] Applicants respectfully point out that the Patent Office has said the Interim Guidelines "do not constitute substantive rulemaking and hence do not have the force and effect of law. They are designed to assist Office personnel in analyzing claimed subject matter for compliance with substantive law. Rejections will be based upon the substantive law, and it is these rejections which are appealable." Department of Commerce, Patent and Trademark Office, *Request for Comments on Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112(l) 'Written Description 'Requirement*, Fed. Reg. Vol. 63, No. 114 (June 15, 1998), page 32639. As such, the examiner's sole reliance on the Guidelines (Office Action mailed February 15, 2002 at pages 4-5) is improper.

specification describes multiple objectives and utilities that are met by the present invention. For example, the claimed nucleic acid molecule is useful in determining the presence of polymorphisms, isolating specific promoter sequences, and to obtain nucleic acid homologues, etc. (*See e.g.*, Specification, beginning at page 33, under heading "Uses of the Agents of the Invention").

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, i.e., the claimed nucleic acid molecule may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed nucleic acid molecule possesses the requisite utility under 35 U.S.C. § 101.

The Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecule. Rather, the Examiner attempts to undermine the existing utilities by stating that these "...are ones which are applicable to the general class of nucleic acids and are not specific to the SEQ ID NO: elected."[2] *See* Final Action at page 3. *See also* Office Action mailed February 15, 2002 at pages 4-5.

In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of

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[2] Applicants note that all sequences are the subject of applicants' invention and that the claims are restricted to SEQ ID NO: 1 because of the Examiner's restriction requirement.

law - there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renshaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Moreover, this position offends the sensibilities. For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicants note that the claimed nucleic acid molecule encompasses many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecule will identify a unique subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid molecule exhibits the requisite utility under 35 U.S.C. § 101.

One of the utilities disclosed in the specification is use of the claimed nucleic acid molecule to identify the presence or absence of a polymorphism. *See* Specification at page 12, lines 14-19. The Examiner argues that this utility, like all of the asserted utilities, is not a specific, substantial, and credible utility, *See* Final Action at page 3, but does not provide any support (legal or factual) for the proposition that detection of polymorphisms is not a legal utility.

This utility is directly analogous to the utilities of a specialized screening assay, *i.e.*, the claimed nucleic acid molecule may be used to locate and measure nucleic acid molecules having specific characteristics within a sample, cell, or organism. The Examiner denigrates this utility by asserting "the general utilities taught by the specification and argued by applicant do not constitute a specific, substantial, and credible utility for the claimed SEQ ID NO's". *See* Final Action at page 3. The Examiner, however, in doing so ignores the fact that SEQ ID NO: 1 has a specific use due to its unique and particular nucleic acid sequence which is at once distinct and separate from all other non-identical nucleic acid sequences. This nucleic acid sequence can be used as a novel research tool which is specific for one type of molecule or characteristic. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." *See* MPEP § 2107 at page 2100-25. The Examiner contradicts this by asserting, "a 'use' to do further research ... is not a specific, substantial, and credible utility under 35 USC 101". *See* Final Action at page 3.

Use of the claimed nucleic acid molecule to detect the presence or absence of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas

chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Information has been obtained about the gas.[3] Likewise, the claimed nucleic acid molecule has utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

The claimed nucleic acid molecule has been asserted to work for a specific, *i.e.*, not vague or unknown benefit – to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acid molecule, not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

In view of the above, Applicants contend that the claimed nucleic acid molecule is supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 1 and 8 under 35 U.S.C. §101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

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[3] For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

C. **The Claimed Nucleic Acids Are Enable By The Specification**

The enablement of the claimed nucleic acid molecule has been challenged. Claims 1 and 8 were erroneously rejected as not enabled by the specification, because the claimed nucleic acid molecule allegedly lacks utility and therefore cannot be enabled. *See* Final Action at page 5. This rejection has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

D. **The Specification Provides An Adequate Written Description of the Claimed Invention**

The adequacy of the written description has been challenged by the Examiner because the nucleic acid molecule of claim 1 is allegedly "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s)...had possession of the claimed invention." *See* Final Action at page 6.

The Examiner does not contest that Applicants have disclosed SEQ ID NO: 1 and, as such, have *per se* met the written description provision of 35 U.S.C. § 112, first paragraph with respect to this sequence. However, the Examiner contends that the specification does not "teach any polypeptide sequence, does not disclose any ORF's, and does not otherwise disclose any information with regard to any polypeptide sequence putatively or possibly encoded by SEQ ID NO: 1." *See* Final Action at page 6. According to the Examiner, claim 1 lacks sufficient written description because "there is no support or evidence that SEQ ID NO: 1 does indeed encode a protein or peptide." *Id.* However, such an assertion is unfounded.

As the Examiner notes, the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, i.e., to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader that the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-Mar-Co.*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, simply because the claimed nucleic acid molecule

may also include mutations, allelic variations, splice variations and the like, does not require that Applicants describe each and every one of these molecules.

Contrary to the Examiner's assertion that the "instant specification fails to teach that SEQ ID NO: 1 encodes any polypeptide, specifically a maize protein", the specification discloses that SEQ ID NO: 1 belongs to the family of *Zea mays* (see sequence listing). *See* Office Action mailed February 15, 2002 at page 8. Furthermore, the Examiner has provided no evidence that a skilled artisan would not readily recognize that Applicants had possession of SEQ ID NO: 1 as of the filing date of the application. The fact that the nucleic acid molecules may comprise additional sequences, or variations, or may even encode non-maize proteins is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the present specification.

The present claim "distinguish[es] the claimed invention from others" and defines "structural features commonly possessed by members of the genus that distinguishes them from others," unlike the claims at issue in *Eli Lilly*. 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997) ("a CDNA is not defined or described by the mere name 'cDNA'...but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA."). Thus, there is no deficiency in the written description support for the claimed invention.

Accordingly, for at least the foregoing reasons, the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, should be reversed.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

Date: March 17, 2003

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APPENDIX A

1. A substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1.

8. A substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1.